SENATE BILL No. 1683

Introduced by Senator Scott

February 24, 2006

An act to add Division 112.6 (commencing with Section 130650) to the Health and Safety Code, relating to pharmaceutical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 1683, as introduced, Scott. Pharmaceutical information: clinical trial data.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would require a pharmaceutical company that sells, delivers, offers for sale, or gives away pharmaceutical drugs within the state to make publicly available every new and ongoing clinical trial, the results of every completed clinical trial, an explanation of noncompletion for any uncompleted clinical trial that the company conducts or sponsors. The bill would authorize the Director of Health Services to adopt additional reporting requirements and would require each subject company to submit an annual report to the Attorney General that certifies that the company is in compliance with the provisions of the bill. The bill would make violation of its provisions subject to a civil penalty of $_____.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. (a) The Legislature finds and declares all of the following:

(1) Recent scandals involving Vioxx, Celebrex, Paxil, and other medications have demonstrated a need for the state to better protect California consumers taking pharmaceutical products.

(2) In some of these scandals, including Vioxx and Paxil, the manufacturers of the drugs had access to clinical trial data demonstrating serious potential adverse side effects or lack of effectiveness, but the manufacturers did not share the data with the general public.

(3) The absence of this information hurts consumers both financially and physically. Research by the federal Food and Drug Administration estimates that Vioxx alone may have caused up to 140,000 cases of coronary heart disease in the United States.

(4) Articles and editorials in leading medical journals and newspapers have highlighted problems with clinical trial reporting beyond outright data suppression, including: the use of a comparison drug at a dosage that is too low to be effective, making the study drug appear superior; the choice of a comparison drug dosage that is too high, making the study drug appear less toxic; the publication of data only from preferential endpoints; the publication of the same data in multiple articles to increase the data's impact; and the use of ghostwriters paid indirectly or directly by the study sponsor to give the sponsor control over the publication's message.

(5) By making sure that all clinical studies on pharmaceutical drugs see the light of day and that the information necessary to understand and critique the studies is available, doctors and other medical professionals will be better equipped to make sound decisions about medicines and patients will be better informed about potential dangers of certain medicines.

(b) It is the intent of the Legislature in enacting this act to require pharmaceutical drug companies to make public the results of all clinical trials conducted on their drugs if those drugs are made available to California consumers.

SEC. 2. Division 112.6 (commencing with Section 130650) is added to the Health and Safety Code, to read:

DIVISION 112.6. PHARMACEUTICAL DRUG RIGHT-TO-KNOW ACT

130650. This division shall be known, and may be cited as the "Pharmaceutical Drug Right-to-Know Act."

130651. For purposes of this chapter, the following definitions shall apply:

(a) "Adverse events" means any negative health outcome occurring in a clinical trial subject during the course of the clinical trial.

(b) "Clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any experiment to test the safety or efficacy of a drug or biological product with one or more human subjects.

(c) "Comparator drug" means an investigational or marketed drug or placebo against which a new drug is being tested and compared.

(d) "Completion date" means the date of the last patient visit necessary for completion of the trial or the date of the first publication of any data from the clinical trial, whichever is first.

(e) "Initiation date" means date of enrollment for the first patient in a clinical trial.

(f) "Pharmaceutical company" means any entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of pharmaceutical drugs, either directly or indirectly, by means of chemical synthesis or by a combination of extraction and chemical synthesis. "Pharmaceutical company" also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of pharmaceutical drugs. "Pharmaceutical company" also includes a person who engages in pharmaceutical detailing, promotional activities, or other marketing of a pharmaceutical drug in this state on behalf of a pharmaceutical company.

(g) "Pharmaceutical drug" means any drug which is approved by the federal Food and Drug Administration and commercially available in the state.

(h) "Principal sponsors" means the entity ultimately responsible for funding the trial, the entity ultimately responsible for designing the trial protocol, and the entity who owns the data generated by the trial.

(i) "Purposes of the trial" means the hypotheses that the trial is testing, including, but not limited to, all of the following:

(1) The drug's effectiveness in treating a specific illness or condition. In this case, the illness or condition shall be named, and what type of effect is being sought shall be specified.

(2) The drug's safety when used to treat a specific illness or condition. In this case, the illness or condition shall be named.

(3) The relative effectiveness or relative safety of the drug in treating a specific illness or condition as compared to another drug. In this case, the illness or condition shall be named, and the effect or adverse events to be compared shall be specified.

(j) "Outcomes of the trial" means the specific measurements that were taken to evaluate the effects the drug and any comparator drug had on trial participants.

(k) "Outcomes to be tested" means the specific measurements that will be taken to evaluate the effects the drug and any comparator drug have on trial participants.

(*l*) "Trial funding sources" means the name of and financial contribution amount for each organization, corporation, individual, or other entity that provides any funding for the clinical trial.

130652. Any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130655, every new and ongoing clinical trial that the company conducts or sponsors for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state. Information required for registration shall include, but not be limited to, all of the following:

(a) The name of the trial.

(b) Commercial and chemical name of all pharmaceutical drugs to be tested, including comparator drugs, if any.

(c) Dosages to be tested for each drug, including dosages of comparator drugs, if any.

(d) Initiation date and expected completion date of the trial.

(e) Purposes of the trial, including the medical condition or conditions to be studied.

(f) Outcomes to be tested, including all time points at which outcome data will be measured.

(g) Trial funding sources.

(h) Number of participants to be enrolled.

(i) A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, preexisting health conditions, and an explanation of why each characteristic was used to include or exclude patients.

(j) Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(k) Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(*l*) Any other information required for clinical trial registration by section 113 of the federal Food and Drug Administration Modernization Act of 1997.

130653. Any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130655, the results of every completed clinical trial that the company has conducted or sponsored for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state. Information necessary to meet this requirement shall include, but not be limited to, all of the following:

(a) The name of the trial.

(b) Commercial and chemical name of all pharmaceutical drugs tested, including comparator drugs, if any.

(c) Dosages tested for each drug, including dosages of comparator drugs, if any.

(d) Initiation and completion dates of the trial.

(e) Purposes of the trial, including the medical condition or conditions studied.

(f) Outcomes of the trial including all time points at which outcome data were measured.

(g) Trial funding sources.

(h) Number of patients initially enrolled in the trial.

(i) Number of patients completing the trial.

(j) A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, preexisting health conditions, and an explanation of why each characteristic was used to include or exclude patients.

(k) Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(*l*) Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(m) Frequency, severity, and nature of all adverse events experienced by trial participants, including participants that did not complete the trial, for each drug.

(n) If the study involved a comparison of two or more pharmaceutical drugs, all information regarding the relative efficacy of each drug and the relative frequency, severity, and nature of all adverse events experienced by trial participants, including participants that did not complete the trial.

(o) If any of the data from the study were published in any form, for each of these publications.

(p) If any of the data from the study were published, the name and employer of each author of the study, including "ghostwriters."

(q) Any financial interest the principal researchers of the study have in the drugs tested or compared in the trial and in the principal sponsors of the trial.

(r) How the information regarding adverse events to the study drug is reflected in the package insert for the drug, including direct quotations from the package insert.

130654. Any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130655, an explanation of noncompletion for any clinical trial that the manufacturer initiates but does not complete for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state. Information required for an explanation of noncompletion shall include, but not be limited to, all of the following:

(a) The name of the trial.

(b) Commercial and chemical name of all pharmaceutical drugs tested, including comparator drugs.

(c) Dosages tested for each drug including dosages of comparator drugs, if any.

(d) Initiation and termination dates of the trial.

(e) Purposes of the trial, including the medical condition or conditions studied.

(f) Reasons for termination of the trial.

(g) Trial funding sources.

(h) Number of patients initially enrolled in the trial.

(i) Number of patients enrolled in the trial on the termination date.

(j) A list of all specific characteristics used to include and exclude people as trial participants, such as gender race, age, and preexisting health conditions and an explanation of why each characteristic was used to include or exclude patients.

(k) Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and email address for public inquiry.

(*l*) Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(m) Frequency, severity, and nature of all adverse events experienced by trial participants.

(n) If the study involved a comparison of two or more pharmaceutical drugs, all information regarding the relative efficacy of each drug and the relative frequency, severity and nature of all adverse events experienced by trial participants, including participants that did not complete the trial, for each drug.

(o) How the information regarding adverse events to the study drug is reflected in the package insert for the drug, including direct quotations from the package insert.

130655. The information required pursuant to Sections 130652, 130653, and 130654 shall be submitted for inclusion on www.clinicaltrials.gov, the Web site administered by the National Institutes of Health pursuant to section 113 of the federal Food and Drug Administration Modernization Act of 1997, or its successor Web site subject, to all of the following conditions:

(a) For clinical trials with a trial initiation date on or after January 1, 2007, the sponsor of the trial shall submit the information required pursuant to Section 130652 to www.clinicaltrials.gov no later than 21 days after the trial's initiation. For ongoing clinical trials with a trial initiation date

before January 1, 2007, the sponsor of the trial shall submit the information required pursuant to Section 130652 to www.clinicaltrials.gov on or before January 22, 2007.

(b) For clinical trials with a trial completion date on or after January 1, 2007, the sponsor of the trial shall submit the information required pursuant to Section 130653 to www.clinicaltrials.gov on or before 90 days from when the pharmaceutical drug is first sold, delivered, or offered for sale, or given away in the state. The publication information required in subdivisions (o) and (p) of Section 130653 shall be updated promptly whenever data from the trial have been included in a new publication. If the trial was registered when it was initiated, any differences between the information reported at that time and the information being submitted upon completion shall be highlighted and explained.

(c) For clinical trials with a noncompletion date on or after January 1, 2007, the sponsor of the trial shall submit the information required by Section 130654 to www.clinicaltrials.gov no later than 21 days after the trial's noncompletion. For clinical trials with a trial noncompletion date before January 1, 2007, the sponsor of the trial shall submit the required information to www.clinicaltrials.gov on or before January 22, 2007.

130657. All information submitted pursuant to this division shall be in plain English to the maximum extent possible, with the goal of being readily understandable by a person who is not a medical professional.

130658. The Director of Health Services may adopt additional reporting requirements and rules for the implementation of this division.

130659. On or before February 1 of each year beginning February 1, 2008, each company subject to this division shall submit a report to the Attorney General certifying that it is in compliance with this section and that the information submitted is accurate and complete.

130660. Failure by a pharmaceutical company to meet all of the requirements of this division shall be deemed a violation of the law and the pharmaceutical company shall be liable for a civil penalty of ____ dollars ($____) per violation. Each clinical trial registration required by, and each clinical trial results disclosure

required that does not fully comply with, this division shall be considered a separate violation for which the pharmaceutical company is liable. Additionally, each day of each violation shall be considered a separate violation for which the pharmaceutical company is liable.

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